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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,639	02/21/2001	Roger Berger	8932-320	7055

20582 7590 03/10/2004

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EXAMINER	
ODLAND, KATHRYN P	
ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 03/10/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/788,639	BERGER, ROGER	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 24-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 24-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *15*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated January 5, 2004. Claims 1-21 and 24-75 are pending.

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 21 have been considered but are moot in view of the new ground(s) of rejection.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Since there are numerous occipital plates for spinal stabilization, a novel feature of the invention should be included in the title.

Claim Objections

3. Claim 10 is objected to because of the following informalities: Claim 9 recites a leg portion with a tapered hole. Claim 10, then recites a diameter of the tapered hole that increases from the backside to the front side. This does not appear consistent with the drawings. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-21 and 24-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howland in US Patent No. 5,545,164 in view of Bono in US Patent No. 5,954,722 or Morrison et al. in US Patent No. 5,981,145.

Regarding claim 1, Howland discloses an occipital plate (such as 440/442) having a front side and a back side, a central portion, two leg portions (generally in the area of 444), a plurality of bone screw holes (510) in the central portion, and at least one clamping portion (444) disposed on the front side proximate a free end of at least one of the leg portions, wherein the plate is bendable (column 13, lines 5-10) to conform to an occiput, as recited throughout the specification with emphasis in column 13 and seen in figures 44-46.

However, Howland does not explicitly recite a bushing where the holes are configured and dimensioned to receive the bushing. On the other hand, Bono and Morrison et al. teach bushings. Moreover, Bono teaches a bushing used in a bone plate. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Howland et al. to include a bushing, as taught by Bono and Morrison et al. for the purpose of properly securing the bone screw to the plate.

Additionally, Howland does not explicitly recite, a Y-shaped plate portion. On the other hand, it would be obvious to one with ordinary skill in the art to modify the generally T-shaped plate be generally Y-shaped or any other shape for the specification of the current application does not demonstrate the criticality for a Y-shape.

Regarding claims 2, 36 and 61, Howland, as modified, discloses that as applied to claims 1, 21 and 51, as well as, a central portion that has an upper portion, a lower portion, and a grooved portion (464) therebetween, the upper portion having one bone screw hole (510), as recited in column 13, lines 5-10 and seen in figures 44 and 46.

Regarding claims 3, 37, and 62, Howland, as modified, discloses that as applied to claims 2, 36, and 51, as well as, a grooved portion that is flexible to permit the upper portion to be disposed at an angle with respect to the lower portion, as recited in column 13, lines 5-10.

Regarding claims 4 and 42, Howland, as modified, discloses that as applied to claims 2 and 21, as well as, leg portions and at least a portion of the central portion that are disposed in nonparallel planes, as recited in column 13, lines 5-10, depending on amount of flexing of the plate.

Regarding claims 5, 43 and 64, Howland, as modified, discloses that as applied to claims 4, 42, and 63. However, Howland does not explicitly recite planes that intersect at an angle of between about 160.degree and about 175.degree. However, given that

recited disclosed in column 13, lines 5-10, the plate is flexible and able to be flexed within the angles claimed.

Regarding claims 6, 44 and 65, Howland, as modified, is capable of that disclosed in claims 5, 42, and 63. Further planes that intersect at an angle of about 170.degree, is also within the scope of the invention, given the flexibility.

Regarding claim 7, Howland, as modified, discloses that as applied to claim 1, as well as, a clamping portion (444) that has a pivot member (such as via 444, 446, etc.) and a clamp plate (444), the clamp plate being pivotable about the pivot member, as recited throughout the specification and seen in figure 45.

Regarding claim 8, Howland, as modified, discloses that as applied to claim 7, as well as, a clamp plate that further has a hole (402), the pivot member being receivable in the hole, as recited in column 13, and seen in figure 45.

Regarding claims 9, 30 and 54, Howland, as modified, discloses that as applied to claims 8, 29 and 51. However, Howland does not explicitly recite a pivot member that further has a tapered portion with serrations, and the leg potion further has a tapered hole with serration, wherein the serrations of the tapered portion positively engage the serrations of the tapered hole. On the other hand, it would be obvious to one with ordinary skill in the art to use serrations for the purpose of non-rotation and secure placement.

Regarding claims 10, 31 and 55, Howland, as modified, discloses that as applied to claims 9, 30 and 54. However, the taper will be consistent for proper securing the clamp assembly and it would be obvious to one with ordinary skill in the art to have the taper accordingly.

Regarding claims 11 and 56, Howland, as modified, discloses that as applied to claims 10 and 51, as well as a clamp plate (444) that is secured to the pivot member (446) with a fastener (448), as recited in column 12, lines 33-46 and seen in figure 45.

Regarding claims 12, 32, and 57, Howland, as modified, discloses that as applied to claims 7, 29 and 51, as well as, a leg portion that additionally has a rod-receiving first recess and the clamping plate additionally having a rod-receiving second recess, the first and second recesses generally opposing each other, as seen in figures 44-46.

Regarding claims 13, 33 and 58, Howland, as modified, discloses that as applied to claims 12, 32 and 57. Further, a second recess is serrated would be obvious to one with ordinary skill in the art for the purpose of non-rotation and proper placement.

Regarding claims 14, 38, and 66, Howland, as modified, discloses that as applied to claims 2, 36, and 51. Further, bone screw holes in the lower portion that are disposed

in a rectangular array, would be obvious to one with ordinary skill in the art, for it is obvious to have the holes in a rectangular array or any configuration that properly secures. Additionally, the current application specification does not recite the criticality of a rectangular array and further shows other configurations in the figures.

Regarding claims 15, 39, and 67, Howland, as modified, discloses that as applied to claims 14, 38, and 66, as well as at least one group of bone screw holes in an array that are disposed along a central axis of the plate extending between the leg portions, as seen in figure 44.

Regarding claims 16, 40, and 68, Howland, as modified, discloses that as applied to claims 15, 39, and 67, as well as, a bone screw hole in the upper portion is that disposed on the central axis, as seen in figure 44.

Regarding claims 17, 41, and 69, Howland, as modified, discloses that as applied to claims 16, 36, and 51, as well as, at least two bone screw holes are disposed coaxially, as seen in figure 44.

Regarding claims 18, 45, and 70, Howland, as modified, discloses that as applied to claims 1, 21, and 51, wherein bushings, as taught by Bono and Morrison et al. and the modification would necessarily permit polyaxial angulation.

Regarding claims 19, 20, 49, 50, 74, and 75, Howland, as modified, discloses that as applied to claims 1, 21, and 51, as well as, a plate that is bendable along at least two generally parallel/perpendicular axes, recited in column 13, lines 5-10.

Regarding claim 21, Howland discloses an occipitocervical fixation system having an occipital plate (such as 440, etc.) having at least one rod clamp portion (such as 444, etc.) and a plate portion with at least one hole (510) for receiving a bone screw, the rod clamp portion having a post (446), a pivotable clamp plate (444) with a hole (402) for receiving the post, as seen in figure 45; at least one bone screw (450); and at least one rod, wherein the rod is retained between the plate portion and the clamp plate is pivotable about the post, as recited throughout the specification and seen in figure 46, for example.

However, Howland does not explicitly recite a plate that further includes an arcurate stepped-in portion adjacent the post and the clamp plate further includes an extension sized and configured to engage the arcurate stepped-in portion. However, this or any other attachment would be obvious to one with ordinary skill in the art, for the purpose of properly securing and fastening the system.

Regarding claims 24, 46, and 71, Howland, as modified, discloses that as applied to claims 18, 45, and 70, as well as, Bono teaches a frustospherical shaped exterior of a busing, as seen in figure 2. Thus, it would be obvious to further modify the invention of

Howland to include a frustospherical shaped exterior of a busing, as taught by Bono for the purpose of proper fit and movement.

Regarding claims 25, 47, and 72, Howland, as modified, discloses that as applied to claims 18, 45, and 70, as well as, Bono teaches a bushing with a slot (46) on a sidewall, as seen in figure 4. Thus, it would be obvious to assure the system of Howland, when modified by Bono, have a bushing with a slot.

Regarding claims 27, 34 and 59, Howland, as modified, discloses that as applied to claims 12, 32 and 57, as well as a rod-receiving recess that has a first recess that has a V-shaped recess, as seen in figure 45.

Regarding claims 28 and 53, Howland, as modified discloses that as applied to claims 21 and 52. Further, an arcurate stepped-in portion that extends through an angle of about 80 degrees to about 120 degrees would fall within the scope of the modification and the current application specification does not demonstrate the criticality for the range.

Regarding claim 29, Howland, as modified discloses that as applied to claim 21, as well as, a plate that includes a posthole (generally at 462, etc.) sized and configures to receive the post (446), as seen in figure 45.

Regarding claims 35 and 60, Howland, as modified discloses that as applied to claims 21 and 51, as well as, a rod that is positionable in the at least one clamp portion by insertion from a top portion of the assembly, as seen in figures 45 and 46.

Regarding claims 48 and 73, Howland, as modified discloses that as applied to claims 47 and 72, as well as, Bono and Morrison et al. teach a sidewall with a ridge. Thus, when modifying the invention of Howland by Bono and Morrison et al. it would be further obvious to include a ridge, for the purpose of properly securing the plate to the screw.

Regarding claim 51, Howland discloses an occipital plate (generally 440) having a front side and a back side, a central portion, and at least one leg portion (generally in the area of 444); at least one bone screw hole (510) in the central portion; at least one pivotable clamping portion (444) disposed on the front side of the at least one leg portion; wherein the at least one leg portion includes a post (446) and the at least one clamping portion includes a pivot member and a clamp plate, the pivot member being sized and configured to mate with the clamp plate and the post hole, as recited throughout the specification, discussed above and seen in figures 44-46..

Regarding claim 52, see that discussed above regarding claim 21.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

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